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January 2, 1986

#21

Mr. Ronald Wilson
Office of the Associate Commissioner
for Health Affairs (HFY-20)
Room 11-46
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

RE: Novafil (4,224,946)
FDA Docket # 85E-0550
and
RE: Novafil (4,246,904)
FDA Docket # 85E-0551

Dear Mr. Wilson:

Transmitted herewith are copies of the applications for Patent Extension of U. S. Patents 4,224,946, issued September 30, 1980 and 4,246,904, issued January 27, 1981. These applications were filed on November 25, 1985 under Title II of Public Law 98-417, the Drug Price Competition and Patent Term Restoration Act of 1984.

These patents claim a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, either one of the subject patents are considered to be eligible for patent term restoration. Thus, a determination of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the applications are provided pursuant to 35 USC 156(d)(2)(A).

C.E. Van Horn

Charles E. Van Horn
Director, Group 120
U. S. Patent and Trademark Office

cc: John J. Hagan
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